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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,334

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Weixing Wu

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EXAMINER

KOSAR, AARON J

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

02/04/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/551,334	<b>Applicant(s)</b> WU ET AL.	
	<b>Examiner</b> AARON J. KOSAR	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/22/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II and the species Sindbis virus in the reply filed on August 27, 2009 is acknowledged. The traversal is on the ground(s) that the claim groups have unity; however, this is not persuasive because Applicant did not distinctly and specifically point out the supposed errors in the restriction. The traversal of the elected species is on the ground(s) that the species are enveloped viruses; however this is not found to be persuasive, because the generic invention is not limited to enveloped viruses and, for the reasons of record, because the viruses are each considered to be structurally dissimilar and differently classified organisms and would have different utility in the art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-38 are pending of which, claims 10-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 30-38 are pending and have been examined on the merits.

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### ***Claim Objections***

Claim 30 is objected to because of the following informalities: In claim 30, in line 5, the phrase “plasma, and” separating the final steps in the method appears to be an inadvertent typographical error and should recite the phrase -- plasma; and --.

Appropriate correction is suggested.

Claims 32, 33, and 35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 30 which is drawn to *a method of illuminating viruses in blood* and which concludes with the step of illuminating the photosensitizer methylene blue-plasma mixture; however, claims 32, 33, and 35 recite method steps (e.g. transfusing filtered plasma/reconstituted blood into a patient) in a method of using the illuminated viruses, but do not further limit a method of illuminating a virus.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 30, in line 2 recites in the method, the step of "separating the plasma from the blood cells"; however, the claim does not recite a preceding plasma or blood cell. There is insufficient antecedent basis for this limitation in the claim and thus it is unclear if Applicant intends for a step, for example, separating the whole blood containing anticoagulant into plasma and blood cells or if another meaning is intended. Clarification is required.

Claims 32, 33, and 35 are indefinite because the claims are unclear how the steps further limit a method of illuminating viruses. In the instant case, claim 30 recites a method of illuminating viruses and concluding with the step of illuminating the methylene blue-plasma mixture; however, claims 32, 33, and 35 are unclear how the steps further limit a method of (i.e. arrive at the conclusion of) illuminating viruses in blood. Clarification is required.

Claim 33 recites in lines 2-3 the term "the whole blood"; however, claim 30, line 2 and claim 33, line 2 each recite "whole blood " and it is unclear from which recited whole blood, if any, Applicant intends for the term to depend. Clarification is required.

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 USC § 112, second paragraph, for the reasons set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saalman (WO 00/59551 A1; 2000) in view of Stedman (U.S. Patent No. 6,177,403; 2001) and Park (U.S. Patent No. 5,516,629; 1996).

A method of illuminating viruses (such as the elected species of Sindbis virus) in blood is claimed - the method comprising the steps of (i) adding anticoagulant into whole blood, (ii) separating plasma from blood cells; (iii) mixing methylene blue with the plasma; and (iv) illuminating the mixture. The dependent claims recite the sources of obtaining the blood and processes of using the illuminated mixture.

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Saalmann teaches a method of exposing viruses to photosensitizers, the method comprising obtaining a body fluid sample containing a virus (including HIV) and separating the sample into blood plasma and corpuscular elements (blood cells); mixing a photosensitizing phenothiazine dye such as methylene blue with the plasma phase of the sample; and then bombarding the plasma with electromagnetic radiation such as visible light (illuminating the methylene blue-plasma mixture). Saalmann also discloses reinfusing the plasma back into the patient as separate fractions or as reconstituted blood (page 4, lines 10-11; page 10 line 11) and performing the reinfusing via a filtering device (page 8, line 18).

Saalmann does not expressly teach providing whole blood with anticoagulant or *Sindbis* virus.

Stedman teaches mixing whole blood with heparin (an anticoagulant) and then separating the heparinized blood's red blood cells from the plasma (col 26, lines 11-14).

Park teaches a method of photodynamically inactivating blood-borne viral and bacterial contaminants, including blood contaminated with Human Immunodeficiency Virus-1 (HIV-1) and Sindbis virus (entire document, for example col 8, lines 29-37).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have also added anticoagulant into the blood or the separated fractions thereof in the method of Saalmann so as to provide an anticoagulant-containing blood sample as adding anticoagulant to whole blood as beneficially taught by Stedman which teaches heparinizing (anticoagulating) blood before separating the blood into plasma and blood cells, making adding heparin (coagulant) to blood an obvious choice in the separating method of Saalmann.

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Saalmann is relied upon for the reasons discussed above. If not expressly taught by Saalmann, based upon the overall beneficial teaching provided by this reference with respect to providing in the method any blood infected with a virus (e.g. page 4, lines 2-3) and, if necessary, based upon the beneficial teaching of Park with respect to providing blood infected with a variety of viruses including Sindbis virus (making the selection of a virus-infected blood or source thereof a mere matter of choice on the part of one of skill in the art), in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable blood, source thereof, or virus contained therein and thus the extent (%) of removal of the virus in the method), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/  
Examiner, Art Unit 1651

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655